

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To: Darryl B Mischlewski 24 Christowel Street CAMBERWELL VIC 3124

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing (day/month/year) 12 JAN 2005		
Applicant's or agent's file reference	FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/AU2004/001454	International filing date (day/month/year) 25 October 2004	Priority date (day/month/year) 24 October 2003
International Patent Classification (IPC) or both national classification and IPC Int. Cl. ⁷ C07J 075/00; A61K 035/22; A61P 5/24; A01K 23/00		
Applicant THORGARD PHARMACEUTICALS (AUST.) PTY LTD et al		

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer R.L. POOLEY Telephone No. (02) 6283 2242
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/AU2004/001454

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

☐ paid additional fees

☐ paid additional fees under protest

☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are three inventions:

1. Claims 1-4 relate to a method of extracting desired chemical species from pregnant animal's urine comprising the use of adsorber materials of a specific particle size and the washing of the adsorber material with a buffer solution having a specific pH. It is considered that this extraction method constitutes a first special technical feature.

2. Claims 5, 7-9 and 11 relate to an apparatus for the collection of valuable chemical species from pregnant animal's urine using a general adsorbent material for said chemical species. The apparatus for collection of valuable chemical species using such a general adsorbent material is considered to constitute a second special technical feature. It is considered that this independent claim for an apparatus is not "specifically designed for carrying out" the process of claims 1-4. The contribution over the prior art made by the apparatus does not correspond to that made by the process of claims 1-4. (See the Patent Examiner's Manual, Volume 1, Part 5, paragraphs 10.12 and 10.14)

3. Claims 6 and 10 relate to an apparatus for the collection of valuable chemical species from pregnant animal's urine using an organic water immiscible solvent for said chemical species. The apparatus for collection of valuable chemical species using an organic water immiscible solvent is considered to constitute a third special technical feature. It is also considered that this independent claim for an apparatus is also not "specifically designed for carrying out" the process of claims 1-4.

Since the abovementioned groups of claims do not share the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☐ all parts

☒ the parts relating to claims Nos. 1-4

**WRITTEN OPINION OF THE
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International application No.

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Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims 1-4	YES
	Claims	NO
Inventive step (IS)	Claims 1-4	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-4	YES
	Claims	NO

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: AU 722739

Novelty (N) and Inventive Step (IS)

Claims 1-4 meet the criteria set forth in PCT Article 33(2) for novelty. The prior art published before the priority date does not disclose extraction of the desired chemical species using "a buffered aqueous solution of pH between 7.5 and 9.5". It is also considered that it is not obvious to the person skilled in the art to consider using a solution of such pH as all the prior art pertains to extraction solutions with a pH around 12 or higher, or non-aqueous solutions. Thus claims 1-4 meet the criteria set out in PCT Article 33(3) with regard to inventive step.

Please also note that there is a P, X document listed in Box VI which was published prior to the international filing date, but later than the priority date claimed.

**WRITTEN OPINION OF THE
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International application No.

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Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
US 2004/0072812	15/April/2004	9/October/2002	9/October/2002

This document discloses all the features of claims 1-4. See the whole document.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>
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**WRITTEN OPINION OF THE
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International application No.

PCT/AU2004/001454

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

It is considered that claim 1 is not fully supported by the description as it refers to the extraction of "desired chemical species". The description only supports the extraction of oestrogens, conjugated estrogens, equine chorionic gonadotropin and follicle stimulant hormone.